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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/877,317 06/17/97 COOK

P ISIS-2508

EXAMINER

HM12/0329

JOSEPH LUCCI
WOOD COCK WASHBURN KURTZ
MACKIEWICZ AND NORRIS
ONE LIBERTY PLACE-46TH FLOOR
PHILADELPHIA PA 19103

MARTINELL, J

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

03/29/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/877,317

Applicant(s)
Cook

Examiner
James Martinell

Group Art Unit
1633



☒ Responsive to communication(s) filed on Feb 26, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) 1-12, 17, 18, 21, and 23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 13-16, 19, 20, and 22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1.5 and 2

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 17, and 23, drawn to PNA-DNA-PNA compositions, classified in class 536, subclass 23.1.
- II. Claims 13-16, 19, 20, and 22, drawn to antisense methods of inhibition of protein expression , classified in class 514, subclass 44.
- III. Claims 18 and 21, drawn to methods of modifying nucleic acids, classified in class 435, subclass 91.53.

The inventions are distinct, each from the other for the following reasons. The compositions of Group I have uses other than in the methods of Groups II and III. For example, the compositions of Group I can be used as probes in a nucleic acid molecular hybridization assay or in affinity chromatography. The methods of Group II can be practiced independently of the methods of Group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by

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their different classification and because of their recognized divergent subject matter restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Lucci on March 3, 1999 a provisional election was made with traverse to prosecute the invention of Group II, claims 13-16, 19, 20, and 22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-12, 17, 18, 21, and 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

References BT, CG, CU, and CV listed on the form PTO-1449 filed September 23, 1997 have not been considered because copies were not filed. Should applicant wish these references to be considered, applicant should submit a new form 1449 listing these

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references, copies of the references, and the appropriate fee
(see 37 CFR §1.97).

The disclosure is objected to because of the following
informalities.

- (a) The status of each of the parent applications should be updated.
- (b) The first two sentences of the specification must be merged in order for all of the parent applications to be mentioned in the first sentence.
- (c) The recitation of "SN92/11339" in the second sentence of the application is incomplete.
- (d) In claim 13, line 11, "include" should be changed to "includes".

Appropriate correction is required.

The following is a quotation of the second paragraph of 35
U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 19, 20, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, and incomplete.

- (a) Claims 19 and 20 are incomplete because they depend from non-elected claim 1
- (b) Claim 19 is indefinite because the instant application does not define what is meant by "RNase H activation".
- (c) Claim 22 is incomplete because it depends from non-elected claims 1, 8, 9, and 10.

Claims 13-16, 19, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application does not adequately teach an effect on any organism by administration of any of the modified PNAs mentioned

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in the claims. Rojanasakul is cited here as evidence that antisense treatment of organisms involves several problems, among them, stability of the oligonucleotide, uptake of the oligonucleotide, and specificity of hybridization of modified oligonucleotides to their intended targets. The instant application does not address these problems in connection with the administration of an antisense agent to an organism.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633.

Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1633 at (703) 308-4242. The faxing of such papers must conform with the rules published in the Official Gazette, 1156 OG 61 (November 16, 1993).

Any inquiry concerning this communication should be directed to J. Martinell at telephone number (703) 308-0296.